

EA And FONSI For

TR 99-007

FINDING OF NO SIGNIFICANT IMPACT

FOR

A threshold of regulation submission by Zeneca Biocides, requesting that 2-methyl-4,5-trimethylene-2-methyl-4,5-trimethylene-4-isothiazolin-3-one, CAS Reg No. 82633-79-2, be exempt from regulation as a food additive under 21 CFR 170.39 when used as a preservative in food-packaging adhesives

The Threshold of Regulation Committee, Center for Food Safety and Applied Nutrition, has determined that granting the proposed use of this substance an exemption will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the requestor in an environmental assessment prepared using the format described in 21 CFR 25.31a(b)(1).

Prepared and Approved by: Andrew J. Zajac
Andrew J. Zajac, Environmental Engineer
Threshold of Regulation Committee

Date: February 24, 1997

925-0181

FONSI 9

ABBREVIATED ENVIRONMENTAL ASSESSMENT

1. Date: FEB 20 1997
2. Name of Applicant/Petitioner:

Zeneca Inc.
Attn: M.E. Burt
3. Address: 1800 Concord Pike
Wilmington, DE 19897
4. Description of Proposed Action

Threshold of Regulation approval for PROMEXAL® X 50 Preservative in food-packaging adhesives. This approval is required and has been requested by customers for the control of microbes in aqueous based adhesives which may be used in food-packaging applications.

PROMEXAL X 50 Preservative, active ingredient, MTI (2-methyl-4,5-trimethylene-4-isothiazolin-3-one), is produced at Zeneca Fine Chemicals Manufacturing Organisation, Grangemouth, Stirlingshire, UK.

PROMEXAL X 50 Preservative will be used by adhesive manufacturers as an antimicrobial adhesive preservative. PROMEXAL X 50 waste should not be generated in this application since all of the product would be used in the production of adhesives. Therefore, disposal of waste PROMEXAL X 50 should not be an issue. However, since PROMEXAL X 50 is regulated by the US EPA (EPA Registration Number 10182-385) under FIFRA, EPA required disposal statements are on product labeling.

We expect that food packaging made with the additive will be used in patterns corresponding to national population density, and will be widely distributed across the country. Consequently, disposal will occur nationwide, with the materials ultimately being deposited in landfills, incinerated or recycled (where possible). Environments potentially affected by disposal would be watersheds or groundwater receiving leachate from land disposal sites and areas subject to air emissions from landfills and incineration sites. Because the additive contains both sulfur and nitrogen, oxides of nitrogen and sulfur may result from incineration of food packaging that contains the additive. However, because of the estimated market volume of the subject additive for the proposed use and the total amount of nitrogen and sulfur already entering the municipal waste stream, granting Promexal X 50 an exemption will not result in a measurable change in incinerator emissions.

5. Identity of Chemical Substance Subject of Proposed Action.

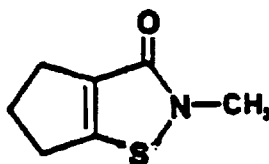
PROMEXAL X 50 Preservative:

Active Ingredient: 2-methyl-4,5-trimethylene-4-isothiazolin-3-one (5% active ingredient content in PROMEXAL X 50)

CAS Registry No.: 82633-79-2

Molecular Weight: 155

Structural Formula:



Physical Description: Pale, clear, straw colored liquid

6. Introduction of Substances into the Environment

- Substances expected to be emitted:

Gaseous Emissions: The volatile organic compounds emitted are essentially xylene and hexane. For each, the theoretical mass emission rate has been shown to be less than 2 kg/hr - the limit as set out in "Environmental Protection Act 1990 Process Guidance Note IPR 4/5 : Batch Manufacture of Organic Chemicals in Multipurpose Plants". The other organic compounds used/produced in the manufacturing process are emitted at significantly lower levels. The annual VOC emission rate at maximum plant capacity has been estimated at 7.5 tonnes per annum, and has been accepted as satisfactory by the SEPA.

The plant is designed to abate mercaptan to below the odor threshold.

The plant is designed to abate HCl to the required concentration limit of 10 mg/m³ (as dimethylamine).

Aqueous Emissions: Various aqueous effluent streams arise from these processes. They are composed mainly of water and a variety of inorganic salts, with some containing acids or bases and minor amounts of organics. These effluents combine with other releases from Grangemouth Works and the resultant mixed stream complies with specific conditions of the trade effluent consent applied by the Forth River Purification Board (now also part of SEPA) thereby ensuring there are no adverse conditions. Each effluent has been tested by the Zeneca Group Environmental Laboratory at Brixham, UK, to ensure there are no biological or fish toxic discharges. Further, the Forth estuary has been routinely surveyed for over 20 years and has demonstrated total compliance with EEC and UK water quality standards.

By early 1997, the Grangemouth Works effluent will be neutralized and biotreated in a newly commissioned effluent treatment plant.

Other wastes: Landfill to registered sites is used only for the disposal of non-chemical general waste. Organic residues arising mainly from solvent recovery and solids from carbon screening are incinerated under contract agreement at audited facilities in full compliance with licensed conditions as applied by the waste disposal authority. Extensive use of solvent recovery is utilized within the PROMEXAL process to minimize organic residues produced.

- Controls exercised:

The controls used to limit gaseous emissions are listed below:

Where possible, pump rather than nitrogen pressure transfers to limit hexane losses. Automatic cut off of nitrogen to limit blowthrough times, also used for hexane transfer. Use of vent condensers, in some cases, serviced with refrigerant. Carbon beds/bleach scrubbing to abate mercaptan. Acid scrubbing for amines. Caustic scrubbing for HCl.

- Citation of and statement of compliance with applicable emission requirements at the national and local level:

Zeneca has been authorized by HM Industrial Pollution Inspectorate, now part of the Scottish Environmental Protection Agency (SEPA), under Section 6 of the 1990 Environmental Protection Act to manufacture PROMEXAL X 50 at its Grangemouth manufacturing site.

- Discussion on the effect that the approval will have on compliance with emission requirements of the site:

The PROMEXAL plant has been expanded recently. The approval requested by this petition will have no foreseen effect on compliance with emission levels on site.

- Yearly market volume of the additive for the proposed use:

Although this product is not yet marketed in the US, it is anticipated that the total yearly market volume will be 5 tons of PROMEXAL X 50 formulated product.

- Amount that will be a component of the finished food-packaging material: The maximum amount of PROMEXAL X 50 in adhesives is 0.3% or 0.015% by weight on an active ingredient basis.

- Concentration of proposed food additive expected to enter the environment at the site of production of food-packaging materials: There is no reasonable expectation that there would be any PROMEXAL X 50 entering the environment at the production site where it is incorporated into adhesive product as a preservative under standard use conditions. It is expected that users will follow EPA label directions which mitigate against environmental exposure.

7. Fate of Emitted Substances in the Environment:

- Physical/Chemical data are referenced in the threshold of regulation request.
- Further documentation of the environmental fate of PROMEXAL X 50, or the active ingredient, MTI, is not required as the amount in the finished food-packaging material will be less than 5-percent-by-weight.

8. Environmental Effect of Released Substances:

Environmental effects data on MTI, the active ingredient in PROMEXAL X 50, are referenced in the threshold of regulation request.

Further documentation of environmental effects data for PROMEXAL X 50 or the active ingredient, MTI, are not required as the amount in the food-packaging material will be less than 5-percent-by-weight.

9. Uses of Resources and Energy:

PROMEXAL X 50 is an antimicrobial whose proposed use is to preserve adhesive compositions. There are other antimicrobials on the market already in use and the use of PROMEXAL X 50 will not materially change the potential uses of the packaging material to which it is added. Further documentation in this area is not required.

Examples of antimicrobial substances currently used in food packaging in the United States that Promexal X 50 will compete with (reference, 21 CFR 175.105):

- 1,2-benzisothiazolin-3-one
- 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one

10. Mitigation Measures:

As PROMEXAL X 50 will be present in food-packaging material at not greater than 5-percent-by-weight, further documentation in this area is not required.

11. Alternatives to this Proposed Action:

As PROMEXAL X 50 will be present in food-packaging material at not greater than 5-percent-by-weight, further documentation in this area is not required.

12. Preparer:

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13. Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm responsible for preparation of the environmental assessment.

Date: FEB 20 1997

Signature: 

Title: Chemical Regulatory Specialist

14. References:

Petition Proposing an Indirect Food Additive Use for PROMEXAL X 50 as a Preservative in Paper Coating Compositions for Components of Paper and Paperboard in Contact with Aqueous and Fatty and Dry Foods.

15. Appendices:

PROMEXAL X 50 -
Physical State: liquid
Color: pale, clear, straw colored
Odor: no appreciable odor
Relative Density: 1.02
pH: 4.8
Viscosity: 1.20 mPaS
Vapor Pressure of Active Ingredient: 2.1×10^{-3} mm Hg, 0.003 Pa at 20C
Water Solubility: >20% w/w at 20C
Partition Coefficient: Log P = 0.6 at 25C

Aquatic LC50: Trout: 96 hr LC50 = 1.8 mg/l
Bluegill: 96 hr LC50 = 2.0 mg/l
Daphnia: 48 hr EC50 = 1.3 mg./

Avian Toxicity: Bobwhite Quail LD50 = 152 mg/kg
Bobwhite Quail Dietary LC50 = > 5620 ppm
Mallard Duck Dietary LC50 = > 5620 ppm

Biodegradability: Biodegradable at concentrations below biocidal level